Fresenius iCare Monitoring System
510(k) Premarket Notification

Summary of Safety and Effectiveness

E. Substantial Equivalence:

NOV 13 2002

1. Is the product a device?

YES - The Fresenius iCare Monitoring System is a device pursuant to 21 CFR §201 [321] (h).

2. Does the new device have the same intended use?

YES – The Indications for Use for the Fresenius iCare Monitoring System is equivalent to that for the Fresenius FDS08 and is as follows:

Intended Use

The Fresenius iCare Monitoring System is a computer-based hemodialysis treatment monitoring system for adjunctive use with the Fresenius 2008 series dialysate delivery system when the patient is attended by trained personnel.

This monitoring system is contraindicated as the sole method of monitoring a patient during hemodialysis.

3. Does the device have technological characteristics that raise new types of safety or effectiveness questions?

NO – The Fresenius iCare Monitoring System is an updated version of the Fresenius FDS08. As such, the technological characteristics of the Fresenius iCare Monitoring System are equivalent to those of the Fresenius FDS08.

4. Does descriptive or performance information demonstrate equivalence?

YES – Fresenius Medical Care North America believes that the information provided in this submission clearly describes the Fresenius iCare Monitoring System and demonstrates that it is substantially equivalent to the Fresenius FDS08.

F. Safety Summary

The iCare Monitoring System validation rigorously tested the features of the Fresenius iCare System. The results of this testing indicate that the iCare System is safe and effective for its intended use.

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G. General Safety and Effectiveness Concerns

The device labeling contains an Operator's Manual, which includes indications for use, cautions and warnings, as well as the general operating instructions required for proper use of the device. In addition, training and support is provided to clinics that use the Fresenius iCare Monitoring System. This information promotes safe and effective use of the device.

Arthur Eilinsfeld
Director of Regulatory Affairs

10/1/02
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2002

Mr. Arthur Eilinsfeld
Director of Regulatory Affairs
Fresenius Medical Care North America
95 Hayden Avenue
LEXINGTON MA 02420

Re: K021060
Trade/Device Name: Fresenius iCare Monitoring System
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 FKP
Dated: August 16, 2002
Received: August 19, 2002

Dear Mr. Eilinsfeld:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Fresenius Medical Care

Indications for Use Statement

Device Name:

Fresenius iCare Monitoring System

Indications for Use:

The Fresenius iCare Monitoring System is a computer-based hemodialysis treatment monitoring system for adjunctive use with the Fresenius 2008 series dialysate delivery system when the patient is attended by trained personnel.

This monitoring system is contraindicated as the sole method of monitoring a patient during hemodialysis.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021060